



## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P13612PC/PC/RO		FOR FURTHER ACTION	See Form PCT/PEA416
International application No. PCT/GB2004/002695	International filing date (day/month/year) 24.06.2004	Priority date (day/month/year) 26.06.2003	
International Patent Classification (IPC) or national classification and IPC A61B1/32, A61B1/31			
Applicant UNIVERSITY OF DUNDEE et Al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 7 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  26.04.2005		Date of completion of this report  20.06.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Manschot, J Telephone No. +31 70 340-4451 	

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# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/GB2004/002695

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

### Description, Pages

1-29 as originally filed

### Claims, Numbers

1-41 filed with telefax on 20.05.2005

### Drawings, Sheets

1/18-18/18 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):
  4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**International application No.  
PCT/GB2004/002695

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 34-41

because:

☒ the said international application, or the said claims Nos. 34-41 relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 34-41

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**International application No.  
PCT/GB2004/002695

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-33
	No: Claims	
Inventive step (IS)	Yes: Claims	1-33
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

**2. Citations and explanations (Rule 70.7):****see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

**PCT/GB2004/002695**

**Section III**

Method claims 34 to 41 defines a method for treatment of the human or animal body by surgery. In particular, the method comprises the steps of inserting and moving a medical device into a body passage (rectum) and expanding the body passage for treatment or diagnostic purposes (see e.g. claim 41). This method, therefore, involves an interaction with the living human or animal body, and comprises a surgical action. Therefore no preliminary international examination is required for the subject-matter of these method claims (see Article 34 (4) (a) (i) PCT and Rule 67.1 (iv) PCT).

**Section V**

1. Reference is made to the following documents:

D1: WO 01/54568 A (STERILIS INC.) 2 August 2001

D2: KAKIZOE ET AL.: "Rectal expander-assisted Transanal Endoscopic Microsurgery in rectal tumors" SURGICAL LAPAROSCOPY AND ENDOSCOPY, vol. 8, no. 2, April 1998 (1998-04), pages 117-119, XP008035719

D3: US 2002/169363 A1 (HEROLD KAREN) 14 November 2002

D4: US-A-5 505 690 (PATTON MICHAEL T ET AL) 9 April 1996

2. The present invention relates to an expander for expanding a body passage. Such devices are well known in the art as exemplified by the above mentioned documents: Document D1 discloses an expander with tubular, distending balloons; D2 is a foldable plastic bottle; D3 concerns a speculum having dilating pivoting blades; and D4 discloses an expander having dilating blades which pivot in an end plate. None of the prior art documents, therefore, discloses or hints at expanding the body passage by controllably elastically deforming an expansion arm. Consequently, the subject-matter of claims 1 to 33 is novel and inventive and meets the requirements of Article 33 (1)-(4) PCT.

**Section VII**

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/GB2004/002695

disclosed in the documents D4 is not mentioned in the description, nor is this document identified therein.

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

Section VIII

1. The embodiments of the invention described on pages 24 to 26 in relation to Figures 52 to 64 and 73 to 81 do not fall within the scope of the claims, since these embodiments do not have an elastically deformable arm. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.



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P.5/11

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LAPORATORY PCT/PTO 20 DEC 2005CLAIMS

1. Medical apparatus adapted for location at least partly within a body passage, the apparatus having a leading end and an area for access from the apparatus into the body passage, at least part of the area spaced from the leading end, and the apparatus being controllably movable between collapse and expansion positions, for expanding the body passage, wherein the apparatus incorporates an expansion device comprising an expansion arm adapted to be moved between a collapsed position and an expansion position by controllably elastically deforming said expansion arm to expand the body passage.
2. Apparatus as claimed in claim 1, wherein the apparatus is adapted to be moved between the collapse and expansion positions in incremental steps.
3. Apparatus as claimed in any preceding claim, wherein the apparatus is controllably movable between fully collapsed and fully expanded positions, and is adapted to be moved to a position between the fully collapsed and fully expanded positions.
4. Apparatus as claimed in any preceding claim, wherein the apparatus is for use in transanal endoscopic microsurgery (TEM).
5. Apparatus as claimed in any preceding claim, wherein the collapse position of the apparatus is a rest position and the expansion position is a stressed position, and wherein the apparatus is adapted to move to the collapse position in the absence of an applied expansion force.

20-05-2005

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P.6/11

31

5 6. Apparatus as claimed in any one of claims 1 to 4, wherein the collapse position of the apparatus is a stressed position and the expansion position is a further stressed position, and wherein the apparatus is adapted to move to the stressed position in the absence of an applied expansion force.

10 7. Apparatus as claimed in any one of claims 1 to 4, wherein the collapse position of the apparatus is a stressed position and the expansion position is a rest position, and wherein the apparatus is adapted to move to the expansion position in the absence of an applied collapse force.

15 8. Apparatus as claimed in any preceding claim, comprising an actuating device including an activating member adapted for moving the apparatus between the collapse and expansion positions.

20 9. Apparatus as claimed in claim 8, wherein the activating member is moveable relative to a remainder of the apparatus.

25 10. Apparatus as claimed in claim 9, wherein the actuating device comprises a screw mechanism including a screw threaded member coupled to the activating member, rotation of the screw threaded member adapted to move the activating member relative to a remainder of the apparatus, thereby moving the apparatus between the collapse and expansion positions.

30

11. Apparatus as claimed in claim 9, wherein the actuating device comprises a ratchet mechanism including



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P. 7/11

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P.8/11

33

end of the guide member is minimised, to facilitate access through the opening.

5 19. Apparatus as claimed in any one of claims 15 to 18, wherein the access area is an elongate opening, of a greater dimension in a direction along a main axis of the guide member than in a direction around a perimeter of the guide member.

10 20. Apparatus as claimed in any one of claims 15 to 19, wherein the access area is an opening extending around at least half of a perimeter of the guide member.

15 21. Apparatus as claimed in any preceding claim, including an inlet at a trailing end thereof for access into the apparatus and to the access area.

20 22. Apparatus as claimed in any one of claims 15 to 21, wherein the expansion arm is mounted on and extends longitudinally with respect to the guide member.

25 23. Apparatus as claimed in any preceding claim, wherein the expansion arm is adapted to adopt a curved shape when in an expansion position.

24. Apparatus as claimed in any preceding claim, wherein the expansion arm is of a shape memory alloy.

30 25. Apparatus as claimed in any preceding claim, wherein the expansion arm is adapted to be moved to the expansion position by heating the device above a transition temperature of the shape memory alloy.

20-05-2005

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P.9/11

34

26. Apparatus as claimed in any one of claims 8 to 25, wherein the expansion device is movable to the expansion position in response to a force applied by the actuation device.

5

27. Apparatus as claimed in any preceding claim, wherein the expansion device comprises at least one inflatable element, adapted to be inflated to move the apparatus to the expansion position.

10

28. Apparatus as claimed in any preceding claim, wherein the expansion device comprises a plurality of inflatable elements, the elements axially spaced with respect to a main axis of the apparatus.

15

29. Apparatus as claimed in claim 27 or 28, wherein the/each elastically deformable expansion arm is coupled to a respective inflatable element.

20

30. Apparatus as claimed in claim 27 or 28, wherein the/each expansion arm is coupled between at least two respective axially spaced inflatable elements.

25

31. Apparatus as claimed in any one of claims 15 to 30, comprising a flexible cover extending between the expansion device and the guide member, for preventing any part of the body passage from damage during movement of the expansion device between the collapse and expansion positions.

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32. Apparatus as claimed in any preceding claim, wherein the expansion device provides a force-feedback to an operator during movement between the collapse and expansion positions.

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P.10/11

35

33. Apparatus as claimed in any preceding claim,  
comprising a device for measuring an expansion force  
exerted on the body passage during movement of the  
apparatus between the collapse and expansion positions.

34. A method of providing access to a body passage, the  
method comprising the steps of:

inserting a medical apparatus at least partly into a  
body passage with the apparatus in a collapse position;

controllably moving the apparatus from the collapse  
position to an expansion position by controllably  
elastically deforming an expansion arm, to expand the  
body passage; and

accessing the body passage through an access area of  
the apparatus, at least part of the access area being  
spaced from a leading end of the apparatus.

35. A method as claimed in claim 34, comprising exerting  
an expansion force on the medical apparatus following  
insertion into the body passage, to move the apparatus to  
the expansion position.

36. A method as claimed in claim 34, comprising exerting  
a collapse force on the medical apparatus, to move the  
apparatus to the collapse position and to restrain the  
apparatus in the collapse position for insertion into the  
body passage, and subsequently releasing the collapse  
force, whereupon the apparatus moves to the expansion  
position.

37. A method as claimed in any one of claims 34 to 36,  
comprising controllably moving the apparatus from the

20-05-2005

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P.11/11

36

expansion position to the collapse position and removing the apparatus from the body passage.

5 38. A method as claimed in claim 37, further comprising rotating the apparatus relative to the body passage, reinserting the apparatus into the body passage and returning the apparatus to the expansion position.

10 39. A method as claimed in any one of claims 34 to 36, comprising returning the apparatus to the collapse position, rotating the apparatus within the body passage, and then returning the apparatus to the expansion position.

15 40. A method as claimed in any one of claims 34 to 39, comprising viewing the body passage through the access area.

20 41. A method as claimed in any one of claims 34 to 40, comprising conducting a diagnostic procedure on the body passage.

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